MONSANTO

MONSANTO COMPANY
800 N. LINDBERGH BLVD.
ST. LOUIS, MISSOURI 63167
PHONE: (314) 694-1000
http://www.monsanto.com

May 5, 2017

Via email to P65Public.Comments@oehha.ca.gov

Ms. Esther Barajas-Ochoa
Regulations Coordinator
California Office of Environmental
Health Hazard Assessment
1001 I Street
Sacramento, CA 95812

Re: Monsanto Company's Comments on
Proposed No Significant Risk Level for Glyphosate

Dear Ms. Vela:

Monsanto Company ("Monsanto") submits the following comments and the enclosed scientific assessment in response to the Office of Environmental Health Hazard Assessment's ("OEHHA") proposed No Significant Risk Level ("NSRL") for glyphosate.

Glyphosate does not cause cancer. Therefore, exposure to glyphosate, at any level, poses "no significant risk" of cancer to humans. OEHHA has no basis to quantify an NSRL from experimental animal studies. Instead, OEHHA must determine that glyphosate exposure at any level "poses no significant risk" under Cal. Health & Safety Code § 25249.10(c) and 27 Cal. Code Regs. § 25701. In other words, the NSRL is infinite.

Glyphosate has been the subject of hundreds of toxicological studies over its more than 40 years of use as an herbicide critical to growing food crops in California and around the world. The overwhelming consensus of regulatory and scientific bodies worldwide is that there is no evidence of any carcinogenicity with respect to glyphosate. The outlier on this issue is the International Agency for Research on Cancer, a working group of which concluded that glyphosate is a "probable carcinogen." Solely based on this determination, OEHHA proposed a "ministerial" listing of glyphosate under Proposition 65.[1]

---

[1] OEHHA, Notice of Intent To List Glyphosate (Sept. 4. 2015).

The IARC working group did not make its conclusion based on "sufficient evidence" in human studies.[2] Instead, it based its conclusion of "sufficient evidence" of carcinogenicity on four animal studies in rodents, which OEHHA found to meet the criteria of the regulations. *See* 27 Cal. Code Regs. § 25306(e) (requiring that a chemical listing be based either on sufficient animal data or sufficient human data).

Yet nearly two dozen other regulatory and scientific bodies, which variously reviewed the *same* four animal studies that the IARC working group reviewed (as well as at least eleven additional animal studies in rodents), reached the opposite conclusion: Glyphosate is *not* shown to be carcinogenic. These include OEHHA in its own independent review of the scientific evidence in 2007, as well as the U.S. Environmental Protection Agency in September 2016— finding that none of the tumors in fifteen different animal studies are related to the administration of glyphosate and concluding that glyphosate should be classified as "not likely to be carcinogenic to humans."[3] Similarly, no less than nine additional regulatory agencies across the globe have conducted assessments *after* the IARC determination and concluded that glyphosate is not carcinogenic to humans. These include the following: Canada's Pest Management Regulatory Agency (2017),[4] European Chemical Agency (ECHA) Committee for Risk Assessment (RAC) (2017),[5] Korean Rural Development Administration (RDA) (2017),[6]

---

2 As to the human studies, IARC found only "limited evidence," which does not support a finding under Proposition 65 that the chemical is known to cause cancer. 27 Cal. Code Regs. § 25306(e). In any event, as discussed in this letter and the enclosed scientific assessment, the data do not demonstrate any human risk of cancer from glyphosate.

3 Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, EPA's Office of Pesticide Programs (Sept. 12, 2016), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0094.

4 Re-evaluation Decision PRVD2017-01, Glyphosate Summary (April 28, 2017), *available at* http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_decisions/rvd2017-01/index-eng.php ("Glyphosate is not genotoxic and is unlikely to pose a human cancer risk.").

5 Glyphosate not classified as a carcinogen by ECHA, ECHA News Release (Mar. 15, 2017), *available at* https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa ("RAC concluded that the available scientific evidence did not meet the criteria to classify glyphosate as a carcinogen, as a mutagen or as toxic for reproduction.").

6 Rural Development News: Safety of glyphosate-diazinon-containing pesticides, Korean Rural Development Administration (Mar. 10, 2017), *available at* http://www.rda.go.kr/board/board.do?mode=view&prgId=day_farmprmninfoEntry&dataNo=100000731828 ("[I]t was concluded that animal testing found no carcinogenic association. … A large-scale of epidemiological studies on glyphosate similarly found no cancer link.").

Australian Pesticides and Veterinary Medicines Authority (APVMA) (2016),[7] New Zealand Environmental Protection Authority (2016),[8] German Federal Institute for Occupational Safety and Health (2016),[9] Joint FAO/WHO Meeting on Pesticide Residues (JMPR) (2016),[10] Japan Food Safety Commission (FSC) (2016),[11] and European Food Safety Authority (2015).[12]

The weight of the scientific evidence demonstrates that IARC incorrectly concluded that there is sufficient evidence of carcinogenicity in animal studies. Most importantly for determining an NSRL, these reviews concluded that no tumors in any of the animal data (including the four studies on which the IARC working group based its conclusion) were related to the administration of glyphosate. As a result, a finite NSRL cannot be extrapolated from these animal studies.

---

7 Regulatory position: consideration of the evidence for a formal reconsideration of glyphosate, Australian Pesticides and Veterinary Medicines Authority (Sept. 2016), *available at* http://apvma.gov.au/sites/default/files/publication/20701-glyphosate-regulatory-position-report-final.pdf ("exposure to glyphosate does not pose a carcinogenic or genotoxic risk to humans").

8 Review of the Evidence Relating to Glyphosate and Carcinogenicity, New Zealand Environmental Protection Authority (August, 2016), *available at* http://www.epa.govt.nz/Publications/EPA_glyphosate_review.pdf ("glyphosate is unlikely to be genotoxic or carcinogenic to humans").

9 CLH Report: Proposal for Harmonised Classification and Labelling, German Federal Institute for Occupational Safety and Health (May 2016), *available at* https://echa.europa.eu/documents/10162/13626/clh_report_glyphosate_en.pdf ("No hazard classification for carcinogenicity is warranted for glyphosate").

10 Summary Report, Joint FAO/WHO Meeting on Pesticide Residues (May 9-13, 2016), *available at* http://www.who.int/foodsafety/jmprsummary2016.pdf?ua=1 ("Glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet").

11 Japan Food Safety Commission (March 2016), *available at* http://www.fsc.go.jp/iken-bosyu/pc3_no_glyphosate_280406.data/pc3_no_glyphosate_280406.pdf ("No neurotoxicity, carcinogenicity, reproductive effect, teratogenicity or genotoxicity was observed").

12 Glyphosate: EFSA updates toxicological profile, EFSA News Release (Nov. 12, 2015) *available at* http://www.efsa.europa.eu/en/press/news/151112 ("glyphosate is unlikely to pose a carcinogenic hazard to humans"). The full EFSA Report can be downloaded here: http://www.efsa.europa.eu/en/efsajournal/pub/4302.

Moreover, OEHHA previously concluded that "[b]ased on the weight of evidence, glyphosate is judged unlikely to pose a cancer hazard to *humans*." [13] In reaching this conclusion, OEHHA referenced a number of studies, including the four studies on which the IARC working group based its designation of glyphosate as a Category 2A chemical. As to the study that OEHHA references to extrapolate a proposed NSRL, OEHHA previously cited the World Health Organization's finding as to that study (and other studies) that "[glyphosate] has no genotoxic potential and there no evidence or carcinogenicity in rats or mice."[14] Additionally, in reaching its conclusion that glyphosate is not likely to pose a cancer risk to humans, OEHHA independently reviewed the three other studies that the IARC monograph referenced, and OEHHA reached a conclusion that directly contradicts IARC's designation.[15] Thus, by OEHHA's own independent conclusion, OEHHA cannot extrapolate or quantify an NSRL, which is based on human cancer risk, from those same animal studies. Nowhere in its proposal for an NSRL does OEHHA address its prior determination, which necessarily requires OEHHA to adopt an NSRL that is infinite and a determination that glyphosate exposure, at any level, poses no significant risk of cancer to humans.

The scientific evidence shows that glyphosate is not a human carcinogen. Monsanto retained a scientific consultant to convene an expert panel to review the IARC working group's assessment of glyphosate. The charge to the experts was to thoroughly review the data in the IARC monograph, assess the scope of the research included or excluded, and publish their conclusions to allow for external review. The experts concluded that "the data do not support IARC's conclusion that glyphosate is a 'probable human carcinogen' and, consistent with previous regulatory assessments, further concluded that glyphosate is unlikely to pose a carcinogenic risk to humans." The expert panel's assessment was peer-reviewed and published in *Critical Reviews in Toxicology*. A copy is attached and incorporated by reference into these comments.

---

[13] OEHHA (2007), Public Health Goal for Glyphosate in Drinking Water (emphasis added). As to the study that OEHHA references to extrapolate a proposed NSRL, OEHHA previously cited the World Health Organization's finding as to that study (and other studies) that "[glyphosate] has no genotoxic potential and there is no evidence of carcinogenicity in rats or mice." *Id.* at 20. Additionally, in reaching its conclusion that glyphosate is not likely to pose a cancer risk to humans, OEHHA independently reviewed the three other studies that IARC referenced, and OEHHA reached a conclusion that directly contradicts that of IARC. *Id.*

[14] *Id.* at 20.

[15] *Id.*

Because glyphosate does not cause cancer in humans, instead of quantifying an NSRL based on animal studies under 27 Cal. Code Regs. § 25703, OEHHA must conclude that there is "no significant risk" of cancer from glyphosate under Cal. Health & Safety Code § 25249.10(c). Under that provision, Proposition 65's warning requirement "shall not apply" when, "based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical," the chemical "poses no significant risk assuming lifetime exposure . . . ."

OEHHA has the authority to make a determination that glyphosate poses no significant risk of cancer to humans, as demonstrated by *Baxter Healthcare Corp. v. Denton*, 120 Cal. App. 4th 333 (2004). In *Baxter,* a medical device manufacturer sued OEHHA for a declaratory judgment that there is no significant risk of cancer to humans from DEHP, which had been listed based on animal studies. The court found that the evidence presented by the manufacturer demonstrated that it was "more probable than not" that exposure to DEHP does not pose a significant risk of cancer to humans. The court distinguished a chemical listing decision, which can be made on the basis of sufficient animal data, and OEHHA's NSRL, which must be based on significant risk of cancer in humans. *Id.* at 352-53. The *Baxter* court held that Section 25249.10(c) and 27 Cal. Code Regs. § 25701 (renumbered from 22 Cal. Code Regs. § 12701) supported the "superior court's conclusion that there is no significant risk that exposure to DEHP causes cancer in humans." *Id.* at 371. Furthermore, the *Baxter* court emphasized that it was not sufficient for OEHHA to counter Baxter's evidence by positing, from the animal studies at issue, that cancer "*might* occur in humans." *Id.* (emphasis in original).

Moreover, 27 Cal. Code Regs. § 25703 requires OEHHA to use scientifically more appropriate assumptions than those that OEHHA has used to develop the proposed NSRL. Specifically, OEHHA must consider a larger set of animal studies, as well as the numerous regulatory reviews assessing such studies, and not merely the four studies that the IARC working group chose to evaluate. OEHHA has authority under 27 Cal. Code Regs. § 25703(a) to consider such broader set of studies and reviews in evaluating an NSRL. Under that provision, OEHHA's assessment is not limited to the specific studies used as the basis for listing the chemical, but instead OEHHA's "assessment shall be based on evidence and standards *of comparable scientific validity* to the evidence and standards which form the scientific basis for listing the chemical as known to the state to cause cancer." *Id.* (emphasis added). In turn, OEHHA's basis for listing glyphosate is IARC's classification of glyphosate as a Category 2A chemical on the basis of sufficient evidence in animals (i.e., rodent studies). OEHHA should consider all available

experimental rodent studies, not just the select few that IARC's working group chose to evaluate.[16] The other studies contradict the conclusions reached by IARC's working group with respect to the four referenced animal studies.

In the case of glyphosate, OEHHA already determined in 2007, on the basis of the same animal studies that IARC's working group identified as supporting its conclusion, that glyphosate is "unlikely to pose a cancer hazard to humans." Based on the weight of the evidence showing that the four animal studies (as well as another eleven animal studies) are not "sufficient evidence" of carcinogenicity, OEHHA's own independent determination about the lack of human carcinogenicity, and the lack of epidemiological data showing any cancer risk to humans, the only appropriate action by OEHHA with respect to Health & Safety Code Section 25249.10(c) is to determine that there is no significant risk of cancer to humans from exposure to glyphosate at any level.

For the reasons discussed above and in the enclosed scientific assessment, Monsanto urges OEHHA to determine, consistent with its prior determinations and those of every other regulatory body to review the question, that exposure to glyphosate *at any level* poses no significant risk of cancer to humans.

Respectfully,

Monsanto Company

By: _____
Dr. Philip W. Miller
Global Corporate Affairs Lead

Enclosure

---

[16] As noted above, there are as many as eleven additional rodent studies, which have been assessed by numerous regulatory agencies, as well as the enclosed scientific assessment, all concluding that glyphosate is not carcinogenic to humans.